

REMARKS

Status of Claims

Claims 1-21 are previously allowed. Claims 22-28 were previously or are now cancelled.

Claim 29 has been amended. Support for amended claim is found throughout the specification and at least in paragraphs [0017], [0055] and [0062-0063]. These amendments and cancellations of claims are made without prejudice.

Claims 1-21 and 29 are pending in this application of which claims 1-21 are allowed. Claim 29 is currently under prosecution and after entry of the foregoing amendment remains subject to examination in this application. No new matter has been added by ways of the foregoing amendment, nor is any new issue of patentability raised. The claim as amended is submitted to place the application for allowance. Accordingly, entry and consideration of this amendment is respectfully requested.

Interview

The undersigned representative would like to thank Examiner Swartz for providing the opportunity to discuss this application on June 30, 2011. A statement of the Substance of Interview as required under 37 C.F.R. §1.33(b) is filed on the even date.

Rejection of claims under 35 USC §112, lack of enablement

In the Action, claims 23-24 are rejected under 35 U.S.C. §112, First Paragraph, as allegedly being not enabled. Applicants traverse the rejection of claims 23-24. Reconsideration of these rejections in view of the remarks set forth herein is respectfully requested.

Applicants dispute the interpretation of the claims in the Action. However, without acquiescing to the asserted grounds of rejection and solely in an effort to expedite prosecution of the pending claims to allowance, Applicants have canceled claims 23-24 which moots the arguments stated in the Action. Reconsideration and withdrawal of the rejection of claims 23-24 is respectfully requested.

Rejection of claims under 35 USC §112, Second Paragraph

Claim 24 has been rejected as being indefinite because it lacks dependency to claim 1. Cancellation of claim 24, moots the grounds for rejection of this claim. Reconsideration and withdrawal of the rejection of claim 24 is respectfully requested.

Rejections under 35 U.S.C. §102(b)

In the Action, claim 29 has been rejected under 35 USC §102 (b) as being anticipated by Khamar et al. (WO02/056898A2) because, according to the Action, the claim reads on a composition on one component, i.e., *Mycobacterium w* as taught by Khamar et al.

Without acquiescing to the asserted grounds of rejection and although Applicants dispute the interpretation of the art in the Action and solely in an effort to expedite prosecution of the pending claim to allowance Applicants have amended claim 29 which moots the arguments stated in the Action. As amended, claim 29 is directed to an adjuvant comprising *Mycobacterium w* and/or a constituent thereof wherein said adjuvant stimulates an immune response against a mixed or conjugated antigen or immunogen wherein the antigen or immunogen is not *Mycobacterium w* or a constituent thereof. Khamar et al., fails to teach an adjuvant comprising *Mycobacterium w* wherein the adjuvant stimulates an immune response against a mixed or conjugated antigen or immunogen.

For the reasons set forth above, reconsideration and withdrawal of the rejection of claim. 29 is respectfully requested.

CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such action is hereby solicited.

Applicants believe that no additional fees are due, however, should Applicants be in error, authorization is hereby granted to charge attorney deposit account no. 03-2410, Order No. 106, for any fees.

A telephonic interview between the Examiner and Applicants' representative below is requested if any issues remain to resolve such issues and/or answer any questions the Examiner may have. Please call the undersigned attorney at 617-345-3691 if it facilitates the prosecution of this application leading to allowance.

Respectfully submitted,
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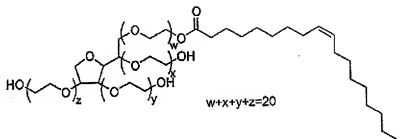
APPENDIX A

CLEAN COPY OF CLAIMS

1. (Previously presented/Allowed) A composition comprising (i) *Mycobacterium w* and/or constituent(s) thereof as an adjuvant, (ii) an antigen, wherein the antigen is not *Mycobacterium w* and/or constituent(s) thereof, and (iii) a pharmaceutically acceptable carrier, wherein the composition results in an enhanced antigen associated immune response of the antigen compared to a composition where component (i) is absent.
2. (Previously presented /Allowed) A composition as claimed claim 1, further comprising other adjuvants.
3. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the *Mycobacterium w* is a killed *Mycobacterium w*.
4. (Previously presented /Allowed) A composition as claimed in claim 3, wherein the killed *Mycobacterium w* is killed by heat, radiation, preferably by autoclaving.
5. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are obtained by sonication.
6. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are obtained by high pressure cell fractionator.
7. (Previously presented) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are obtained by osmotic pressure gradient.
8. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are obtained from the *Mycobacterium w* by extraction.
16. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are extracted from the *Mycobacterium w* by organic solvents.
17. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are extracted using solvents selected from the group consisting of chloroform, ethanol, methanol, acetone, phenol, isopropyl alcohol, acetic acid, urea,

and hexane.

18. (Previously presented /Allowed) A composition as claimed in claim 1 wherein the constituent(s) of *Mycobacterium w* is/are obtained by enzymatic treatment,
19. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are obtained by using enzyme lyticase and/or pronase.
20. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the constituent(s) of *Mycobacterium w* is/are substantially water insoluble.
21. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the *Mycobacterium w* is a non-pathogenic, fast growing, cultivable, atypical *Mycobacterium*, with biochemical properties and growth characteristics substantially similar those belonging to Runyons group IV class of *Mycobacteria*.
22. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the *Mycobacterium w* is urease negative, does not hydrolyse a compound of the formula below, does not produce niacin, and provides positive response to nitrate reduction test,



22. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the *Mycobacterium w* and/or constituents thereof are mixed, formulated, conjugated, primed, fused and/or linked with the antigen.
23. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the antigen is selected from the group consisting of one or more peptides, one or more polypeptides, one or more cells, one or more cell extracts, one or more polysaccharides, one or more polysaccharide conjugates, one or more lipids, one or more glycolipids, one or more carbohydrates, one or more proteins, one or more viruses, one or more viral extracts, and one or

more nucleic acids.

24. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the antigen(s) is isolated from an infectious agent selected from the group consisting of virus, bacterium, fungus and parasites.

25. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the antigen(s) is a tumor associated antigen.

26. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the antigen is a tumor specific antigen.

27. (Previously presented /Allowed) A composition as claimed in claim 1, wherein the antigen(s) is an allergen.

22-28. (Cancelled)

29. (Currently amended) An adjuvant comprising *Mycobacterium w* and/or a constituent thereof wherein said adjuvant stimulates an immune response against a mixed or conjugated antigen or immunogen wherein the antigen or immunogen is not *Mycobacterium w* or a constituent thereof.